

ANALYTE DETECTION

The present invention claims priority to U.S. Provisional Application Serial Number 60/243,854 filed October 27, 2000 and is a Continuation-in-Part U.S. Patent Application Serial Number 09/393,552, filed September 17, 1999 and U.S. Patent Application Serial Number 09/698,306, filed October 27, 2000, each of which is hereby incorporated by reference in their entireties.

FIELD OF THE INVENTION

The present invention relates to analyte detection test systems, including test systems for the oral detection of analytes in saliva. The present invention also provides compositions and methods for storing and distribution of multiple assay tests and compositions and methods for measuring the concentration of analytes in a sample.

BACKGROUND OF THE INVENTION

Advances in detection technologies have made it possible to detect a wide variety of substances in tissue and fluid samples from various organisms. For example, tests are available for qualitative and quantitative detection of glucose, proteins, illicit drugs, cancer markers, cholesterol, pathogens, and other materials in human tissue and fluid samples.

However, many of the available tests are too expensive, cumbersome, complex, or dangerous for routine or frequent usage. For example, many of the tests rely on electronic equipment that is too complex or expensive for use by individuals outside of a laboratory or clinical setting. Additionally, many individuals have an aversion to certain types of sample testing procedures, such as blood and urine testing, and would not be willing to self-administer such assay tests.

The art is in need of detection assay tests for the detection of a wide variety of analytes that adequately combine ease of use, small size, speed, accuracy, low cost, durability (*e.g.*, temperature stability and shelf life), safety and interpretability, and that are designed for widespread distribution and use. Furthermore, delivery systems for

packaging, storing, carrying, preserving, and otherwise maintaining tests are needed to provide adequate ease of use, discrete use, accessibility, and durability of tests.

SUMMARY OF THE INVENTION

5 The present invention relates to analyte detection test systems, including test systems for the oral detection of analytes in saliva. The present invention also provides compositions and methods for storing multiple assay tests and compositions and methods for measuring the concentration of analytes in a sample.

10 For example, the present invention provides analyte detection assay tests for use in detecting the presence of an analyte in saliva. In some embodiments, the tests are configured for oral use (i.e., at least a portion of the assay test is placed into the mouth and contacted with saliva). In some preferred embodiments, the tests are in the form of a test strip. In some embodiments, the test strip comprises an absorbent reaction pad at one end. In some preferred embodiments, the reaction pad contains reactants that create a detectable signal in the presence of an analyte. In some such
15 embodiments, the reaction pad is configured to produce a detectable signal during or after the placement of the reaction pad into the mouth to collect saliva samples. In some preferred embodiments, the detectable signal comprises the formation of a color. In other preferred embodiments, the detectable signal comprises a change in color.

20 The present invention also provides a system comprising a plurality of test assays for analyzing a sample for the presence of an analyte. In some embodiments, the system comprises a plurality of assay tests within a delivery system, wherein the delivery system is configured to prevent the assay tests from being exposed to the environment. In some embodiments, the delivery system is configured to dispense the plurality of assay tests individually (e.g., one at a time). In some embodiments, the
25 delivery system is configured to dispense the plurality of assay tests individually without exposing the remaining assay tests (i.e., the tests that have not yet been dispensed) to the environment. In some preferred embodiments, the delivery system comprises a desiccant. In some embodiments, the delivery system comprises a

desiccant entrained polymer storage container. In some embodiments, the delivery system is entirely lacking a desiccant.

The present invention further provides a system comprising a diagnostic device for analyzing saliva for the presence of an analyte, with the diagnostic device comprising: a solid support; one or more collection sites attached to a first portion of the solid support, wherein the collection site is configured to collect a saliva sample; one or more reaction sites (e.g., containing agents that produce a detectable signal in the presence of an analyte) attached to a second portion of the solid support, wherein the reaction sites produce a detectable signal in the presence of the analyte; wherein the solid support, collection site, and reaction sites are contained within a single device (i.e., a "lateral flow" device). In some embodiments, no solid support is provided (i.e., the test is made of only a collection site and reaction agents). In some embodiments, the collection site and reaction sites may be in contact with one another (e.g., an absorbent material layered onto or integrated with reaction agents). Thus, in some embodiments the first portion and second portion of the solid support may define partially or entirely overlapping regions of the solid support. In some embodiments of the present invention, multiple collection sites and multiple reactions sites are used. The plurality of collection sites find use, for example, in detecting different threshold concentrations of analyte (e.g., a first collection site that detects 0.4% of analyte in saliva and a second collection site that detects 0.8% of analyte in saliva), different detectable readouts (e.g., different colors or a first collection site that shows a color and a second collection site that produces a symbol, shape, or word), different read-out formats (e.g., a first collection site that uses an on/off readout and a second collection site that uses a gradient readout), different detection purposes (e.g., detection versus indicator [to test if the assay is working properly] or detection of different analytes) and the like.

In some embodiments of the present invention, the diagnostic device comprises a thickness X cm, a width Y cm, and a length Z cm, wherein $X * Y * Z$ is less than 12 cm^3 , preferably less than 2 cm^3 and more preferably less than 1 cm^3 , although